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August 30, 2010

VIA ECF AND FEDERAL EXPRESS

Magistrate E. Thomas Boyle
United States District Court, Eastern District of New York
Long Island Courthouse
100 Federal Plaza
Central Islip, New York 11722

**Re: Medical Instruments Development, Inc. v. Cook Incorporated, et al.
Civil Action No. 09-1409 (JFB)(ETB)**

Dear Judge Boyle:

We represent plaintiff Medical Instruments Development, Inc. ("MIDI") in the above-referenced action, and write in response to the letter motion by defendants Cook, Inc. and Cook Medical, Inc. (collectively, "Cook"), submitted August 24, 2010 (the "August 24 Motion"), seeking to modify the Stipulated Protective Order entered herein on December 14, 2009 (the "Stipulated Protective Order").

A. Preliminary Statement

This case is about the design of catheters used in the biliary system (which comprises the gall bladder and related organs and ducts through which bile is formed and carried.) In particular, this case involves improvements in the design of catheters that are used in what are known as ERCP procedures. These procedures involve placing a catheter into the biliary tract under fluoroscopy, and introducing dye and/or an instrument through the catheter to diagnose and/or treat problems in the biliary tract. The procedure usually takes 30-60 minutes, and the catheter is then removed.

Cook's portrayal of NanoVibronix's products and patents as involving the design or development of catheters is false and misleading. NanoVibronix does not design, manufacture, or sell catheters. NanoVibronix, as the name suggests, makes and sells products that apply ultrasound waves which aid in treating soft tissue injury and which reduce the buildup of bacteria on devices that are left in the body for extended periods of time. In other words, NanoVibronix products are used to keep long duration medical implants clean.

Cook's attempt to preclude Dr. Jacob from having access to confidential information is based on gross misstatements of fact. MIDI's counsel kept nothing of relevance from Cook, and nothing that would impact the appropriateness of Dr. Jacob having access to confidential

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information. Cook knew full well about Dr. Jacob's unrelated work with NanoVibronix long before it entered into the Stipulated Protective Order, which allowed Dr. Jacob to review confidential Cook documents. In fact, *Cook's own Senior Vice President*, Mr. Jerry French, invited Dr. Jacob to Cook's offices six months *before* MIDI filed this lawsuit, to discuss NanoVibronix's unrelated technology. (Declaration of Dr. Jacob, dated August 30, 2010 ("Jacob Decl."), submitted herewith, at ¶ 5.)

One use for NanoVibronix products is to clip onto a urinary catheter in order *to prevent the buildup of bacteria* on the catheter. However, urinary catheters are "indwelling", meaning they stay in the body for extended periods of time, and thus are subject to the buildup of bacteria. In contrast, endoscopic catheters, which are at issue in this case, are not indwelling. As such, no confidential information to be obtained from Cook regarding the design, development, or marketing of the accused products would aid in NanoVibronix's business. In fact, in the eight (8) years that Nonvibronix has existed, none of its products has been used with gastrointestinal ("GI") catheters. (Id. at ¶ 7.)

It is telling that Cook's executives who attended the October 2008 meeting with NanoVibronix never raised in this case the issue of Dr. Jacob's work with NanoVibronix during the ten (10) month period since the Stipulated Protective Order was first negotiated. That is because NanoVibronix's products relate to an *entirely different segment* of Cook's business from the one involved in this case. In other words, while NanoVibronix's products could be used to prevent bacteria buildup on devices produced by Cook's *Urinary* business, this case involves Cook's *gastrointestinal* endoscopy business. (Jacob Decl., at ¶¶ 4-5, 7.) No employees from Cook's GI division were present at the October 2008 meeting with Dr. Jacob because there were absolutely no GI applications to discuss with Cook with respect to NanoVibronix. (Id. ¶ 5.)

B. The Patents in Suit Deal With Different Technology Than the NanoVibronix Products and Patents and There is No Risk of Harm to Cook

Before precluding an individual from access to documents, courts consider "1) whether the person receiving the confidential information is involved in competitive decision making or scientific research relating to the subject matter of the patent, 2) the risk of inadvertent disclosure of proprietary information, 3) the hardship imposed by the restriction, 4) the timing of the remedy and, 5) the scope of the remedy." *Infosint S.A. v. H. Lundbeck A.S.*, 2007 WL 1467784, at *3 (S.D.N.Y. May 16, 2007) (citation omitted). Cook's motion fails on each of these counts.

Dr. Jacob is *not* involved in any competitive decision making or scientific research relating to the subject matter of the patents-in-suit. (Jacob Decl. ¶ 2.) As such, there is no risk of inadvertent disclosure of confidential information. Dr. Jacob also has no plans to be involved with the business at issue in this case, and would be willing to enter an undertaking to refrain from such involvement (i.e., with any business involving the design and development of multi-lumen catheters) for a period of one (1) year from the conclusion of this case. (Jacob Decl. at ¶ 9.)

Cook's August 24 Motion distorts the facts by suggesting that both NanoVibronix's products, as evidenced by NanoVibronix's patents, and the accused products relate to catheters generally. That is false. Notably, Cook fails to attach any of the patents in suit, which would allow the Court to see what this case actually involves in terms of technology. Exhibit A hereto is one of the six related patents-in-suit. The claims of the patents-in-suit are straightforward, and

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involve the invention of catheters having multiple lumens (i.e., passageways within them) for use in endoscopic procedures, under fluoroscopy, in the biliary tract. In contrast, NanoVibronix's products and patents relate to the use of ultrasound to prevent bacteria from attaching to "indwelling" medical devices, one of which could be an indwelling catheter. A side-by-side comparison of the nature of the inventions shows that NanoVibronix's patents are in fact unrelated to those in suit. (See Exhibit B hereto.) In other words, even though NanoVibronix products can be used with indwelling implants, NanoVibronix is no more concerned with the internal structure of such implants than a maker of a car wash is concerned with the design of the car's engine. Quite simply, nothing obtained from Cook regarding the biliary catheters at issue in this case could aid in the design, development, or sale of NanoVibronix's products. (Jacob Decl. at ¶¶ 1, 2, 4, 7.)

The burden and timing of Cook's request to modify the protective order also weighs heavily in MIDI's favor. MIDI is Dr. Jacob's company, has no employees other than Dr. Jacob, and sells no products. Dr. Jacob is a practicing gastroenterologist. (Jacob Decl. at ¶ 3.) It is undeniable that Dr. Jacob has unique and expert understanding of the technology at issue in this case, and is a critical resource to MIDI's defense. Cook raised these issues *almost a year* after the protective order was negotiated, and a mere *two weeks* before document production was to be substantially complete. Cook has since held hostage its *entire* electronic document production, and is in default of its obligations to substantially complete its production by August 27, 2010.

Cook's argument that it was duped and that MIDI failed to disclose relevant facts or information in October 2009 is frivolous. Cook's own Senior Vice President was aware of Dr. Jacob's work with NanoVibronix six (6) months before this suit was filed. NanoVibronix has had a web site since before this litigation began, which lists Dr. Jacob as the CEO and describes its products. See www.nanovibronix.com. In addition, the document requests propounded to Dr. Jacob request documents *relating to the patents-in-suit*. Documents relating to NanoVibronix, including its patents, are irrelevant and nonresponsive. (The NanoVibronix patents cited by Cook are public documents in any case.)

Cook's throw-away arguments about Dr. Jacob's involvement with other medical companies should similarly be dismissed. Exhibit C hereto outlines why those companies' products and businesses involve wholly different technologies and do not overlap with this case.

Accordingly, MIDI respectfully requests that the Court deny Cook's untimely request to modify the Stipulated Protective Order. MIDI respectfully requests a hearing at which Dr. Jacob could testify in person regarding the foregoing.

Respectfully submitted,



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cc: James R. Ferguson, Mayer Brown LLP (via email and ECF)
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